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Stress, and the Risk of Preterm Delivery

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Preterm delivery (that is, delivery that is, del	elivery prior to 27 comple	ated weeks of gestat	ion) has prove	ed to be a remarkably
intractable problem in the V				
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defense women as a group				
delivery rates are higher th				
and women may work righ				
assess the effect of various				
seeking prenatal care at Wi	ilford Hall Medical Cente	r. The role of cardio	ovascular reac	tivity in the stress
response and how this affect	cts risk of preterm deliver	y will also be exam	ined. Recruit	ment, now complete,
took longer than anticipate	d due to a high rate of ine	ligibles. We propos	se to complete	the analyses under a
no-cost extension.	-		_	
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DOD Final Report

(4) INTRODUCTION:

Preterm birth is a major cause of perinatal morbidity and mortality. Nationally about 8%-10% of all deliveries are preterm but the rates in subgroups of the population range from 4% -- which is the rate in many other developed countries -- to as high as 18%. Established risk factors, such as black race and low socioeconomic status, explain less than a third of spontaneous preterm births, so there is a considerable interest in identifying significant new determinants of premature delivery. Currently, the potential roles of psychosocial stress and physical strain have attracted attention. These factors may be especially relevant for women who have a marked hemodynamic response to stress.

The overall goal of this study is to examine the effects of physical and psychosocial stress as risk factors for preterm birth among an ethnically diverse population of active duty military women recruited from the prenatal clinc at Wilford Hall Medical Center during their first trimester and followed to delivery. A secondary goal is to evaluate the role of the maternal circulatory response to stress in raising the risk for preterm delivery.

(5) **BODY**:

As we described in previous annual reports, we have encountered a substantial number of ineligibles in our target population, due largely to women who were transferring to another base or leaving the service entirely prior to their expected due date. We had not anticipated this in planning the study and projecting the rate of accrual. As a consequence, when we reached Year 4, at which point recruitment was scheduled to be completed, we had a total of only 641 participants, considerably short of the enrollment target of 1000 women.

We faced a dilemma. We could adhere to the study timeline, necessarily accepting a smaller sample and hence less statistical power, or we could extend recruitment into Year 4 in order to achieve a sample size closer to our initial goal. This last is the option we preferred, especially given the importance of analyzing data for subgroups of the population (e.g., race, age). We are therefore requesting a no-cost extension of the study to cover an additional 9 months, until June 30, 2001. Assuming the DOD agrees, we would submit a supplemental final report at that time. There will of course be no further contact with study subjects although delivery records for the last participants to be enrolled may be reviewed during this period.

Following is a record of our progress to date. In last year's report we described the headway on Tasks 8-11 (Tasks 1-7 having been completed). Below is an update on Tasks 8-11 as well as a status report on Tasks 12-15.

Task 8 - Enroll subjects

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A total of 841 subjects have been enrolled, 200 more than at the end of last year. Of these 683 have completed the baseline questionnaire, 598 have completed both baseline and follow-up questionnaires, and 429 have completed the cardio monitoring. As reported last year, participation in the cardiovascular testing is averaging at best 70%. Subjects claim they are too busy but offers of flexible scheduling did not meet with success.

Task 9 - Enter questionnaires into database

Thus far questionnaire data have been entered for approximately 700 participants. Logic and range checks by the investigators have uncovered no errors.

Task 10 - Integrate psychophysiological data

All of the cardiomonitoring data have been inegrated into the main data files.

Task 11 - Abstract medical records

Records have been abstracted for 590 of the 841 women enrolled.

Task 12 - Travel

The PI plans to make a "close-out" visit to San Antonio at the end of November.

Task 13 - Clean data files

A major focus of our recent work has been on reviewing the data files to insure that all of the data collected have been entered into the computer or, in the case of the cardiac monitoring data, integrated into the main file. The task is virtually completed, with the exception of materials from the final participants.

Task 14 - Statistical Analyses

Although we did begin conducting preliminary analyses on a subset of the entire cohort, we became concerned that the impressions we formed might bias our approach to analysis of the complete cohort. We decided to wait until the full data set was ready before proceeding any further. Therefore, at this time, we are presenting no analytic results. Now that the last subjects are enrolled, we should be able to finalize the data set and begin the actual analyses very shortly.

Task 15 - Preparation of manuscripts and final report awaits results of the full analyses.

(6) KEY RESEARCH ACCOMPLISHMENTS:

- Have assembled a large and diverse cohort of pregnant military women who should contribute very useful data on many aspects of the research question.
- The high response rate among eligible women helps to insure validity of the data collected.
- The data set on cardioresponsivity among pregnant women is virtually unique, both in nature and size.

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None as yet.

(7) CONCLUSIONS:

None as yet.

(8) REFERENCES:

N/A

(9) APPENDICES:

N/A

(10) BINDING:

N/A

(11) FINAL REPORTS:

Since we have not conducted analyses, there are no publications or meeting abstracts based on this study.

Personnel supported by the study:

Maureen Hatch, PhD Trudy Berkowitz, PhD Robert Lapinski, PhD Teresa James, PhD, RN Nora Ervin, RN, MA